U.S. FOOD & DRUG ADMINISTRATION

Investigations Operations Manual 2022

Office of Regulatory Affairs
Office of Operations

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Foreword 2022

The *Investigations Operations Manual* (IOM) is the primary operational reference for FDA employees who perform field activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.

Other FDA manuals and field instructions supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of field activities. In such cases, your division management must be informed and concur with any significant departures from the IOM.

The 2022 version of the IOM contains important changes which clarify or present new information and procedures. As with each new edition of the IOM, please take time to review sections of the manual for changes which may apply to your work. Additions to the IOM are highlighted in light gray.

The IOM is also posted on ORA's Internet Website https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual, with all graphics included.

The COVID-19 pandemic continues to be a paradigm-shifting public health event. In May 2021, FDA issued a report titled, "Resiliency Roadmap for FDA Inspectional Oversight," outlining the agency's inspectional activities during the COVID-19 pandemic and its detailed plan to move toward a more consistent state of operations. From the beginning of this public health emergency, ORA's innovation and resiliency in the face of challenges has highlighted our true commitment to fulfilling the agency's mission to protect and promote the public health. Additionally, 2021 marked the first milestone of the IOM Refresh Project, a cover to cover, all-inclusive review of the IOM, with completion of the Chapter 8 refresh in July and initiation of the Chapters 1 and 2 refresh. In 2022 we will continue to use the new tools and alternative inspectional activities developed in response to the public health emergency to support oversight of regulated industries and agency decision making. As these new tools continue to be developed and refined, we will capture the processes and procedures across programs in the IOM.

The IOM is published hard copy annually. Until the IOM Refresh Project is completed, future updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as ORA's official document of record.

ORA leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2023 edition of the IOM including recommended changes, deletions, and additions to the IOM may be sent via e-mail to IOM@FDA.HHS.GOV. Suggestions are accepted from within the agency, our state and local partners, industry and consumers. All changes are reviewed by the IOM Committee, which is composed of a cross-functional group consisting of representatives from each commodity area in addition to imports, recalls, and policy.

Thank you for your continued exceptional work and commitment to protecting and promoting the health and well-being of the American people. It is an honor serving with you.

Judith A. McMeekin, Pharm.D.

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs

In August 2021, ORA published its five-year Strategic Plan covering FY2022 – 2025, which outlines ORA's direction and approach to accomplish our mission and meet our vision.

Vision

Public health is protected, promoted, and advanced.

Mission

Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products.

Ultimate Outcome

Protect consumers and patients from injury or illness from FDA-regulated products while ensuring timely access to safe and quality products.

Core Values

ORA's core values define the organization's "character" and inform its actions and decisions.

Accountability
Commitment to Public Health
Communication
Inclusion, Diversity, Equity, and Accessibility
Integrity and Respect
Quality

Judith A. McMeekin, Pharm.D.

Associate Commissioner for Regulatory Affairs

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CONTENTS 2022

CHAPTER 8 - INVESTIGATIONS

APPENDIX

INDEX

NOTES

5.2.2.8 - Concurrent Administrative, Civil, and Criminal Actions

It may be appropriate to seek administrative and/or civil remedies against a firm or individual under investigation for criminal violations. There are many issues involved in determining whether such actions may proceed concurrently, or whether certain actions should proceed first. Each situation must be evaluated on an individual basis. If administrative and/or civil remedies are under consideration against a firm or individual also under investigation for criminal violations, representatives from the Center responsible for evaluating the administrative and/or regulatory action should meet with the Office of Criminal Investigations Headquarters staff to discuss issues related to the timing of administrative, civil, and criminal actions. The Office of Criminal Investigations and other components of FDA may share information subject to the reservations set out earlier.

5.2.2.9 - Working with a Grand Jury

Finally, if you are assigned to work with a grand jury, you should not participate in a regulatory inspection or other regulatory matter involving the same firm or individual(s). Such participation is contrary to long standing agency policy, might be unlawful, and could result in sanctions against the investigator and the agency. You should not participate in any regulatory matters that could result in improper disclosure of grand jury information, even after the grand jury investigation is closed. Grand jury proceedings remain secret even after they are concluded. Under no circumstances should you undertake such participation without first obtaining clearance from the Department of Justice attorney or the Office of Chief Counsel attorney assigned to the grand jury case. See IOM 2.2.7.3 for additional information on Grand Jury proceedings.

5.2.3 - REPORTS OF OBSERVATIONS

The FDA 483, Inspectional Observations (see Exhibit 5-5) and the FDA 4056 Produce Farm Inspection Observations (See Exhibit 5-18) is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts (see IOM 5.2.3.2) which were observed during the inspection. These observations are made when in the investigator's **"judgment",** conditions or practices observed, indicate that any food, drug, device, or cosmetic have been adulterated or are being prepared, packed, or held under conditions whereby they may become adulterated or rendered injurious to health. The issuance of written inspectional observations is mandated by law and ORA policy.

Be alert for specific guidance in assignments or Compliance Programs which may supplement the following general instructions.

All FDA-483s and FDA 4056s should adhere to the following general principles:

1. Observations which are listed should be significant and correlate to regulated products or processes being inspected.
2. Observations of questionable significance should not be listed on the FDA-483 and FDA 4056, but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation. This discussion will be detailed in the EIR.

All FDA-483s and FDA 4056s should have the following characteristics to be useful and credible documents:

1. Each observation should be clear and specific.
2. Each should be significant. Length is not necessarily synonymous with significance.
3. Observations should not be repetitious.
4. The observations should be ranked in order of significance.
5. All copies of the FDA-483 and FDA 4056 should be legible.

If an observation made during a prior inspection has not been corrected or is a recurring observation, it is appropriate to note this on the FDA 483 and FDA 4056.

Investigators and analysts should make every reasonable effort to discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when the FDA 483 or FDA 4056 is issued. This discussion should include those observations, which may be written on the FDA 483 or FDA 4056 and those that will only be discussed with management during the closeout meeting. Industry may use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made during the inspection process. Investigators are encouraged to verify the establishment's completed corrective actions as long as the verification does not unreasonably extend the duration of the inspection.

Corrective actions observed during a produce safety inspection are noted on the FDA 4056. Corrective actions not related to a significant observation are noted in the inspection notes and in the EIR. For annotations of the FDA 4056, refer to Section 5.2.3.4 - Annotation of the FDA 483 and the FDA 4056.

Include the results of confirmed positive environmental samples on the FDA-483 or the FDA 4056 if results are known prior to closeout for food inspections. The investigator should not prolong the inspection if the results are not known prior to close-out of the inspection.

There may be instances where same day discussion of observations may not be possible due to the volume of documents collected and document review reveals observations on a different day than the documents were collected or in other circumstances. When these instances occur immediately prior to the conclusion of the inspection the lack of a daily discussion of observations does not preclude listing of significant observations which were not previously discussed on the FDA 483 or the FDA 4056.